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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,883	01/24/2002	Morten Lorentz Pedersen	PEDERSEN=1A	5403
1444	7590	05/28/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/053,883	PEDERSEN, MORTEN LORENTZ	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kenneth R Horlick	1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 86-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-85 and 94-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/08/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Applicant's election without traverse of Group I, claims 1-85 and 94-105, in the paper filed 04/20/04 is acknowledged.
2. Claims 86-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 04/20/04.
3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are drawn to a method of producing a single-stranded polynucleotide tag using a nicking endonuclease.
4. Claim 24 is objected to because of the following informality: a space is missing in part iiib between "polynucleotide" and "comprising". Correction is required.
5. Claims 1-85 and 94-105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A) These claims are confusing because it cannot be determined what action(s) is required in the final step of independent claim 1, "obtaining at least one single stranded polynucleotide tag". Firstly, it is unclear what is encompassed by

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"obtaining"; that is, by what action one "obtains" said tag. Secondly, it is unclear what is encompassed by a "tag"; although this term is also used in the preamble, it cannot be determined from the claim as a whole what single stranded polynucleotide is to be "obtained", and is considered to be a "tag". Clarification is required.

B) Regarding claims 14 and 40, the language "preferably" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are required in the claimed invention. See MPEP § 2173.05(d).

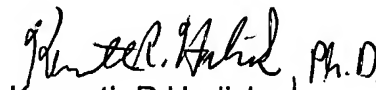
6. Claims 1-85 and 94-105 are free of the prior art, but are rejected for other reasons. No claims are allowable. The claims require the steps of: providing a double-stranded polynucleotide; cleaving only one of the strands of said polynucleotide with a cleavage agent such as a nicking endonuclease; and obtaining at least one single-stranded polynucleotide tag. The closest prior art is considered to be Jack et al. (US 6,660,475), corresponding to pre-grant publication US 2003/0022317 which was made of record by applicant. While Jack et al. disclose a method comprising the first two steps of instant claim 1, neither Jack et al. nor any other prior art teaches or suggests the additional third step of "obtaining at least one single-stranded polynucleotide tag" (although as noted above it is unclear exactly what is encompassed in said third step). Bitinaite (US 2003/0194736), while not prior art, is made of record as it appears to disclose subject matter overlapping with the instant invention.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick, Ph.D.  
Primary Examiner  
Art Unit 1637

05/26/04